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Report Highlights:
Romanian's role as a biotech promoter is clearly in jeopardy, despite the continued support from farmers, and a core group of pro-biotech GOR officials. Local subsidiaries of seed companies have committed to GOR regulators, to meet or in some cases exceed Romania's regulatory requirements, in order to maintain their position on the Romanian market. Given the pressure from the EU, and Romania's weakened bargaining position, this compliance may not be enough to salvage GMO cultivation in Romania.

Includes PSD Changes: No
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I. EXECUTIVE SUMMARY

Invoking pressure from the EU and Romania's weakened bargaining position, GOR representatives recently indicated that the permit for commercial cultivation of herbicide resistant soybeans in Romania is in jeopardy for the 2006 crop year, despite the obvious economic and environmental advantages of the technology. There is an informed and positive opinion among growers regarding biotech soybeans. In MY2004/05, roughly 50,000 hectares of biotech soybeans led to record yields and for the first time Romania turned into a net exporter of vegetable protein that soybeans provide.

AgBucharest has constantly made the argument that, in order to be successful, Romania's government must step up with additional resources to properly regulate the crop in a way that meets the EU requirements. Romania has shown that it can successfully grow, process and market products of agricultural biotechnology that are as safe as any conventionally produced crops, but still needs to improve their regulatory controls.

II. BIOTECHNOLOGY TRADE AND PRODUCTION

Since 2000, Romania, which is expected to join the European Union in 2007, has pioneered the planting of biotech crops, especially soybeans. The first approval for commercial planting of GM soybeans (Glycine max. line GTS 40-3-2) tolerant to glufosinate herbicide was issued by the Romanian Biosafety Commission in accordance with the GOR Ordinance 49/2000.

In 2001, about 15,000 hectares of biotech soybeans were planted and the figure steadily climbed as farmers saw the advantages of the new technology, especially given Romania's huge weed reserve. In 2004, roughly 50,000 hectares of biotech soybeans led to record yields, while the local affiliates of US biotech companies reported unprecedented high demand for seeds for the just completed 2005 spring campaign. Growers are well aware that they can benefit by continuing to produce GM soybeans, as there is a great protein deficit in the EU.

In recent years, field trials were approved for a number of genetically engineered crops, including BT potato, sugar beet, and corn. In 2005, variety testing is being conducted in the national network for a herbicide-resistant corn hybrid (NK603).

III. BIOTECHNOLOGY POLICY

GOR efforts to bring its regulatory capacity into line with EU rules and international agreements resulted in the passage of Law 214 of April 19, 2002, effective from May 2002, which enforces and amends GOR Ordinance 49/2000 on obtaining, testing, utilization, and commercialization of GMOs, as well as products derived from GMOs. The Law provides the main framework for bio-engineered products in Romania. Two other pieces of legislation relevant to biotech-related issues are: (1) GOR Decision 106/February 2002 on labeling food derived from GMOs, or containing genetically modified additives and (2) Minister of Agriculture's Order 462/2003, effective from July 2003, with provisions aimed at tracing biotech products.

By the end of 2005, in accordance with its EU accession commitments, Romania should adopt the new legislation on traceability and labeling of food products deriving from GMOs.

The National Authority for Biotech-related Issues

According to Law 214/2002, the competent authorities in implementing and enforcing all activities related to the use of GMOs, and all activities concerning the deliberate release of GMOs are: (1) the Ministry for Environment and Water Management, responsible for the issuance of authorizations/permits and carrying out the post-control of all related activities (the National Authority, NA); (2) the Ministry of Agriculture, Forests and Rural Development; (3) The Ministry of Health and Family; (4) the National Authority for Consumer Protection.

Additionally, the National Biosafety Commission (NBC), an independent scientific body, advises the Ministry of Environment during the decision making process on biotech policy. The NBC consists of twelve scientists with relevant backgrounds who are members of the Romanian Academy or representatives of research institutes in life sciences, agriculture or medicine.

Approval Procedures

Law 214/2002 stipulates that, the user shall submit to the National Authority, prior to the utilization of any GMO, notification containing at least the information specified by Law 214 (see below). After receiving the notification, the NA will inform and consult with the public regarding the received notification and consult the Biosafety Commission, which will then evaluate the environmental and agricultural impact of such use. The NA will then also request specific assessments from the Ministry of Health and the National Authority for Consumer Protection (which is responsible for food and feed safety) on the impacts of such use on human health.

The NA (the Ministry of Environment and Water Management) must respond to the notifier within a period of 90 days after receipt of the notification whether or not the received notification is in compliance with the current legislation. The notifier may be required to submit additional information. If the proposed activity does not comply with the legislation in effect, the notification is rejected. The 90-day period referred to does not include any periods of time during which the NA: (a) is awaiting further information requested from the notifier, (b) is awaiting the approval of the Biosafety Commission; (c) is conducting public hearings. If the National Authority considers that sufficient evidence has already been gathered through the previous release of certain genetically modified organisms into the environment, it can decide to apply simplified approval procedures. The notifier may proceed with the proposed activity only after obtaining the NA authorization, and it must observe the conditions specified in the authorization. In-country field tests are required prior to granting the commercial status to biotech crops.

Monitoring and Enforcement

According Law 214/2002, the NA officially issues the approval for releasing a specified genetically modified organism into the environment, while relevant departments are responsible for assessing different types of risk conduct post-approval surveillance to check compliance with authorization requirements.

Violations of Law 214/2002 provisions may become infringements according to the penal law and they are punished with a fine (from approximately $300 to $3000 at the current exchange rate) and/or temporary or final suspension of the activity, on a case by case basis. Specialized personnel authorized by the Ministry Agriculture, Waters, Forests and Environment, Ministry of Public Health and Family and the National Authority for Consumer Protection enforce the sanctions provided by the law. Law 214/2002 also states that if damage results from activities regulated through this law that is detrimental to human or

animal health, to biological diversity or to the environment, the user is responsible for the damage. The nature and scope of the damage are to be established by a commission of experts appointed by the National Authority.

Labeling

According to Law 214/2002, the producer is responsible for labeling biotech products placed on the market. This complies with EU legislation and regulations 1/39/98, 49/2000, and 50/2000. The notification submitted to the NA requires the applicant to provide a description of the envisaged conditions for placing the product on the market, including use, handling, and a proposal for labeling and packaging which should comply with the requirements stipulated by Law 214/2002. The label shall clearly state if the genetically modified organism is present. The label bearing the inscription "This product contains genetically modified organisms" is compulsory. There is currently no law or regulation governing the use of labels such as biotech-free, non-biotech, GMO-free, or non-GMO, Law 214/2002 states that within a period of 10 years procedures for such labeling will be established.

The GOR Decision 106/February 2002 - further detailed in its accompanying Methodological Norm 7/2002 - provides more detail on the labeling methodology of foods obtained from biotechnology or containing genetically modified additives derived from GMOs. Interestingly, this norm is narrowed to foodstuffs delivered as such to the final consumer and to processed food entirely or partially obtained from: (i) genetically modified soybean and/or (ii) genetically modified corn. "Product derived from GM Soybean" or "product derived from GM corn" must be clearly written on the label. These additional labeling requirements can be ignored if the content of biotech soybean or corn is less than 1 percent of total ingredients.

Traceability

Tracking biotech products in Romania has become stricter and more rigorous lately from the regulatory perspective. Traceability is required as a consequence of the labeling requirements provided by Law 214/2002 and GOR Decision 106/2002, brought in line EU directives.

In July 2003, the Minister of Agriculture, Waters, Forests and Environment issued its Order 462 which requires all farmers using seeds for biotech crops to report the area planted with such seeds and the yields obtained. More specifically, all individuals/companies that cultivate biotech crops must submit two declarations to the Directorate for Agriculture and Rural Development of the Ministry of Agriculture, Waters, Forests and Environment, the first one within 10 days after sowing is completed, while the second one within 10 days after harvest. The first declaration must describe the name of the crop, area cultivated, and the origin of the seed (whether acquired via procurement or own production). The second declaration must include the name of the plant, the production obtained and its destination (seed for sowing or consumption).

The regulation on traceability requires companies involved in this business, when using or handling biotech products, to submit and keep information at each stage of placing them on the market. Companies are responsible for ensuring that a tracking system is in place.

Testing

Prior to being accepted for commercial cultivation and use (food, processing and feed), any transgenic variety should be first approved for experimental environmental release (field trials). Currently, there is only one corn hybrid, tolerant to glyphosate herbicide (NK603), approved for testing on about 1 HA in the network of the State Institute for Variety Trials and Registration (ISTIS).

Commercially approved transformation events are being reauthorized for testing every year, even in the particular case of hybrid/variety registration tests carried out by the State Institute for Variety Trials and Registration. Required paperwork of the notifier is extremely time-consuming in this respect, as the NA calls for all regulatory agencies' re-issuance of approvals, including the ones with multiyear validity (e.g, Ministry of Health's case).

Table of Approved Biotechnology Products in Romania (2005)

Crop	Trait Category	Applicant(s)	Event	Trait Description	Approved for
Soybeans/Glycine max.	Herbicide Tolerance	Monsanto, Pioneer	GTS 40-3-2	Glufosinate tolerant	Field Trials; commercial cultivation and processing for food and feed use
Corn/ Zea mays	Herbicide Tolerance	Pioneer	NK-603	Glufosinate tolerant	Field trials

Notification Dossier

The notification must include:
-- a technical dossier providing specified information for carrying out the environmental risk assessment, especially: (i) general information on the notifier, including information on personnel and training; (ii) information regarding the genetically modified organism/organisms; (iii) information regarding the conditions of the release and the characteristics of the potential recipient environment; (iv) information regarding the impact of the genetically modified organism/organisms on the environment; (v) a monitoring plan, to identify the effects of the genetically modified organism/organisms on human health and environment; (vi) information on control and corrective methods, waste treatment and emergency response plans; (vii) a summary of the dossier.
-- the environmental risk assessment study together with any bibliographic references and indications of the methods used;
-- information regarding the results of the release of the same genetically modified organisms or of the same combinations of genetically modified organisms on the territory of Romania or elsewhere.

The notifier may refer to the data or the results from the notifications previously submitted by other notifiers, provided that the information, data and results are not confidential or the notifier has their consent. Simplified procedures may apply for GMOs already notified and/or approved in EU members and in OECD countries. In this situation, the notifier will present: (i) either a copy of the notification summary submitted by the national competent authorities in the member states to EU and OECD; (ii) or a copy of the EU and OECD documents which approve the release of the genetically modified organism on the territory

of the member states.

Co-existence

Currently, Romanian authorities have not developed any co-existence rules, as the only transgenic crop approved for commercial cultivation is soybean. Nonetheless, this is expected to change very soon and the EU-line to be adopted, especially given that the Ministry of Agriculture recently stated its priority to encourage ecological (organic) agronomic practices. Organic products are not restricted by CAP quotas and, being labor-intensive, are assessed to be able to absorb in the middle-term, the social shocks of an agricultural sector struggling to adapt itself to meet the new competitiveness requirements of the enlarged common market.

Rules Governing the Movement and International Trade of Transgenic Products

Romania is signatory to the Cartagena Protocol on Biosafety, according to the Ratification Law 59/March 2003. Although the Protocol requires an exporting country to seek consent from an importing country only prior to the first shipment (first trans-boundary movement) of a living modified organism (LMO) intended for intentional introduction into the environment, the Romanian national legislation exceeds this framework and requires companies to adhere to complete biotech product importation procedures (as described below) for every shipment of biotech seeds entering Romania for planting. This represents a real challenge facing local subsidiaries of U.S. biotech companies, forced every year to notify separately **each import of a commercially approved transformation event**.

Romanian national legislation (Law 214/2002) provides that the following information must be presented to the competent national authority (i.e., Ministry of Environment) in notifications concerning documented authorization every time import/export activities of genetically modified organisms are to be performed:

a) Name, address and contact info of the exporter.
b) Name, address and contact info of the importer.
c) Name and identity of the living modified organism, as well as the domestic classification, if any, of the biosafety level of the living modified organism in the State of export.
d) Intended date or dates of the trans-boundary movement, if known.
e) Taxonomic status, common name, point of collection or acquisition, and characteristics of recipient organism or parental organisms related to biosafety.
f) Centers of origin and centers of genetic diversity, if known, of the recipient organism and/or the parental organisms and a description of the habitats where the organisms may persist or proliferate.
g) Taxonomic status, common name, point of collection or acquisition, and characteristics of the donor organism or organisms related to biosafety.
h) Description of the nucleic acid or the modification introduced, the technique used, and the resulting characteristics of the living modified organism.
i) Intended use of the living modified organism or products thereof, namely, processed materials that are of living modified organism origin, containing detectable novel combinations of replicable genetic material obtained through the use of modern biotechnology.
j) Quantity or volume of the living modified organism to be transferred.
k) A previous and existing risk assessment report.
l) Suggested methods for the safe handling, storage, transport and use, including packaging, labeling, documentation, disposal and contingency procedures, where appropriate.

m) Regulatory status of the living modified organism within the State of export and, if the living modified organism is banned in the State of export, the reason or reasons for the ban.
n) Result and purpose of any notification by the exporter to other States regarding the living modified organism to be transferred.
o) A declaration that the above-mentioned information is factually correct.

Trade Barriers

Commercialization of herbicide resistant soybean in Romania is currently hindered by technical barriers related to the manner in which the Romanian authorities implement the Cartagena Protocol (see section on Rules Governing the Movement and International Trade of Transgenic Products) as well as related to an excessive interpretation of the traceability concept. Regarding the latter, the NA conditions the release of the annual approval for commercial cultivation to the notifying seed companies by receiving the list of locations where transgenic soy seeds will be planted. As the whole paperwork is done prior to the actual importation, the seed companies cannot possibly anticipate, in a free market and in an agricultural business model, affected by numerous variables, where precisely and to whom they will sell the products. Once the list of locations at the county level is communicated to NA, as per NA's requirement, it cannot be changed without going again through the entire approval process, with all regulatory Ministries and Agencies.

Another condition laid down to the two seed companies in the Approval issued in 2005, is to provide contact information for the buyers of the harvest. This is another example of an ~~abusive~~ excessive interpretation of the traceability requirements, as the seed company does not have control over the harvested product. The Companies only have the obligation to provide their customers all relevant information about the legal requirements related to biotech crop regime prior to concluding the Sales-Purchase contract.

Intellectual Property Rights

Although this aspect is regulated in Romania via a number of laws and Government Decisions (Law 285/2004 on copyright and connected rights, GD 1424/2003 for approving the National Strategy in Intellectual Property Rights, GD on the Organization of the State Office for Inventions and Trademarks, etc.), the company that was issued the initial approval for importation for commercial planting of the GM soybeans (Glycine max. line GTS 40-3-2) tolerant to glufosinate herbicide in 2002 does not collect royalties, because it did not register the patent in the first year when the technology was introduced into Romania.

IV. MARKETING ISSUES

Despite repeated attempts by a number of anti-biotech organizations to influence public opinion through sensational newspaper headlines, consumers' hostility towards bioengineered food is superficial and there are good chances to increase the acceptance of GMO crops by providing scientifically sound information.

V. CAPACITY BUILDING AND OUTREACH

A well-defined biotechnology program funded by USAID with technical assistance from FAS is currently on-going in Romania with the objective of helping Romania explore ways of coming into the EU with a viable biotech industry and support farmers who are successfully producing and marketing their products in an EU-compliant system. This effort targets primarily high-level political biotech policymakers and has resulted in various activities in

CY2004 and 2005 (policy roundtable discussions, fieldtrips to farms using biotechnology, a study tour in Spain[1]). Additionally, an educational campaign was conducted in May-June of this year, with the aim of explaining to farmers, via town hall meetings, about the national and EU regulatory system as well as their obligations pertaining from this system.

In order to support Romania's capacity to properly implement biotech regulation and innovation, funds for the purchase of biotech lab equipment at Banat Agricultural University were allocated from the joint USDA/USAID Agricultural Development and Policy Support Project to support Romania's ability to evaluate biotech products. (Note: Banat's Lab is currently seeking accreditation as a reference laboratory).

During FY2006, six Romanian young scientists have been selected for training in U.S. universities on biotech-related issues, under the Borlaug Program funding.

With the goal to facilitate a balanced, open dialogue and provide broader availability of scientific information about agricultural biotechnology to both the media and everyday consumers, Romanian press representatives have been selected to participate in the Media Study Tour organized by the International Grains Council in 2004 and 2005, an event about which our office received excellent references.

Complementary programs are being sponsored by the State Department under various initiatives (International Visitor Program – IVP, Voluntary Visitor Program – VolVis) and a recently approved biotech outreach for a broad public educational campaign to reach the organizations of farmers, compound feeders, poultry and swine producers and oilseed crushers. The proposed program builds on existing contacts, local expertise and USAID and FAS matching funds.

Between March 6-12, 2005, a Romanian official took part, together with counterparts from new EU member states (Cyprus, Estonia, the Czech Rep., Latvia, Poland, Slovakia, Slovenia and Hungary) in a biotech study tour in US, sponsored by the US Department of State under a Voluntary Visitor (VolVis) Program. The program aimed at introducing officials from these countries to the US regulatory system of modern agricultural biotechnology, specifically to aspects related to testing, registration and utilization of genetically modified crops. This was achieved through an intense five-day agenda of various meetings of the group with the federal agencies with competences in biotech, as well as a field trip.

[1] A team of Romanian officials from various GOR ministries and agencies with roles in regulating biotech products, led by USDA/FAS Bucharest staff, traveled at the end of September in central and northeastern Spain to first-hand witness how biotech crops are regulated and monitored, especially from the perspective of the new EU legislative framework for labeling, traceability and placing on the market of GM food and feed (Regs 1829/03 and 1830/03), which became fully applicable on April 18, 2004. The agencies/bodies represented to this event were the Ministry of Waters and Environment (the biotech competent authority in Romania), the Ministry of Agriculture, Forests and Rural Development, the National Authority for Consumer Protection, the Biosafety Commission. FAS Madrid facilitated what was unanimously found to be a very productive program for the study tour. By meeting with their Spanish counterparts, the Romanian regulators were extensively explained about the evaluation of GMOs in Spain and the biotech approval process in EU, recently resumed.